CHAPTER VII

DRUG UTILIZATION REVIEW PROGRAM AND DISEASE STATE MANAGEMENT

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OVERVIEW

Purpose and Scope of the DUR Program

State and federal legislation created the directive for the Virginia Medicaid Drug Utilization Review (DUR) Program. The purpose of the DMAS OBRA '90 DUR Program is to assure that prescriptions for outpatient drugs are appropriate, medically necessary, and are not likely to cause adverse medical conditions. OBRA '90 further requires that the DUR Program be designed to educate physicians and pharmacists to reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. DMAS has established a DUR Board to review and approve drug use criteria and standards for both retrospective and prospective DUR; apply these criteria and standards in the performance of DUR activities; review and report the results of DURs; and recommend and evaluate educational intervention programs.

Retrospective DUR (RetroDUR) is required only for outpatients by OBRA '90. However, because of the previous State legislative mandate for nursing facility retrospective DUR, nursing facility patients will also be included in the retrospective component of the DUR Program. Certain criteria used for the nursing facility population will be tailored to the needs of the elderly; the data for the outpatient and nursing facility populations will be analyzed and reported separately.

Prospective DUR (ProDUR), which includes prospective review, patient counseling, and patient profiling, is required only for outpatients. Patient counseling is not required for inpatients of a hospital or institution where a nurse or other caregiver authorized by the Commonwealth is administering the medication.

The impact of the DUR Program on Medicaid providers will vary. The retrospective component primarily is focused on prescribing patterns and is likely to have more of an effect on physicians and other prescribing providers. The pharmacist is responsible for performing the activities required for the prospective component. As a result, ProDUR will affect pharmacy providers to a greater degree than prescribing providers.

RETROSPECTIVE DUR COMPONENT

Overview

The retrospective component of the DUR Program consists of two parts:

- Retrospective claim review
- Provider education

Retrospective DUR Computerized Claim Analyses

OBRA '90 mandates that the following problems be addressed in the retrospective component of the DUR Program:

- Therapeutic appropriateness;
- Overutilization and underutilization;
- Appropriate use of generic products;
- Therapeutic duplication;
- Drug-disease contraindications;
- Drug-drug interactions;
- Incorrect drug dosage or duration of drug treatment; and
- Clinical abuse/misuse.

The DUR Board has selected retrospective DUR criteria that are representative of clinically important issues. The focus of these criteria is on high-risk, high-volume, and high-cost drugs. In addition, certain criteria have been tailored to specific populations; different criteria are used for ambulatory outpatient recipients than for elderly nursing facility recipients. The criteria will be updated periodically to include new products and to reflect changing needs as well as patterns identified through the DUR analyses and follow-up.

The retrospective component of the DUR Program is performed at the direction of DMAS through the computer applications available from the DMAS retrospective DUR computer analysis contractor. The provider education functions will also be the responsibility of DMAS, with input and guidance from the DUR Board.

After the claims data are analyzed, profiles containing complete claim information (pharmacy, hospital, prescriber, and laboratory claims data) will be generated for the recipients who do not meet the DUR criteria. These exception profiles will be produced in such a way that the identity of the recipient and providers is not apparent. The profiles will be reviewed by members of the DUR Committee to determine whether or not to send an intervention letter to the provider. The DUR Board will determine the content of the intervention letters.

Retrospective DUR Criteria - Nursing Facility Recipients

Certain criteria for the retrospective DUR analysis of pharmacy claims data for nursing facility recipients are based upon criteria developed specifically for the geriatric population. These age specific criteria were developed by the University of Maryland's Center for Drug Policy and the Philadelphia College of Pharmacy and Science's Geriatric Pharmacy Institute through a grant from the Health Care Financing Administration (HCFA). The criteria will

be edited as needed to make them consistent with the current edition of *Drug Regimen Review: A Process Guide for Pharmacists* (American Society of Consultant Pharmacists, Alexandria, VA) and HCFA's interpretive guidelines for nursing facility regulations on "unnecessary drugs" and "antipsychotic drugs." The criteria set includes the following areas:

- Angiotensin converting enzyme inhibitors;
- Antipsychotics;
- Benzodiazepines;
- Calcium channel blockers;
- Digoxin;
- Histamine H_2 receptor antagonists; and
- Nonsteroidal anti-inflammatory drugs.

The problem areas covered by the criteria noted above include:

- Dosage;
- Duration of therapy;
- Drug interactions; and
- Therapeutic duplication

Retrospective DUR Criteria - General Outpatient Recipients

The criteria for the DUR analysis of pharmacy claims data for general outpatient recipients are based upon the criteria developed by the DMAS retrospective DUR computer analysis contractor. The DMAS DUR Board has selected general classes of retrospective DUR criteria that are representative of clinically important issues; the focus of these criteria is on high-risk, high-volume, and high-cost drugs. The criteria cover the areas listed in Exhibit VII.1.

Educational Program

Several educational approaches will be used in the retrospective component of the DUR Program, including

- Letters to individual providers outlining specific or potential therapeutic problem; and
- Continuing education seminars.

The purpose of these general communications is to provide information on the findings of and to solicit feedback on the issues and outcomes related to the DUR Program.

Letters to individual providers outlining specific or potential therapeutic problems determined through the application of the DUR criteria will also be used. In those cases where a patient's drug therapy falls outside of the criteria approved by the DUR Board, a letter citing authority for the generally accepted therapeutic recommendations will be sent to the prescribing provider and the dispensing pharmacist (or in the case of nursing facility patients, the dispensing and/or consultant pharmacist). The providers may also be requested to provide clarifying information and justification. While it is hoped that these efforts will promote judicious and cost-conscious use of drugs, the thrust of the DUR Program interventions will be educational and informative, not punitive. Finally, DMAS will work with the various state pharmacy and medical associations to provide suggestions, and, when requested, expertise for DUR-related seminar topics for continuing education purposes.

PROSPECTIVE DUR COMPONENT

Overview

The prospective component of the DUR Program consists of three parts:

- ProDUR screening through the DMAS MMIS computer programming;
- On-line, real-time notice to the pharmacist; and
- Patient counseling.

Since it is possible to perform the ProDUR screening function via a computer, DMAS has chosen to use this approach to facilitate the process. The pharmacist will perform all ProDUR activities at the time a prescription is dispensed, applying the following general precepts:

- ProDUR screening shall be performed **before** all prescriptions for outpatient Virginia Medicaid recipients are filled; and
- The pharmacist may use his or her professional judgement as to the depth of counseling required for prescription refills.

Since pharmacy providers will be performing the ProDUR screenings, it is important that pharmacists discuss questions resulting from the prospective screening directly with the prescriber and/or recipient. Specific concerns may also be communicated to the DUR Program Administrator. Clarification of existing criteria and the need to develop new criteria or replace existing criteria are examples of such concerns.

Prospective DUR Screening Criteria

OBRA '90 requires that the following types of problems be addressed in the prospective component of the DUR Program:

- Therapeutic duplication;
- Drug-disease contraindications;
- Drug-drug interactions;
- Incorrect drug dosage or duration of drug treatment;
- Drug-allergy interactions; and
- Clinical abuse/misuse.

ProDUR activities are being carried out in Virginia's fee-for-service Medicaid Program as proposed by HCFA. Implementation of the mandated prospective component of the OBRA '90 DUR Program will be an evolutionary process. That is, the requirements for the DUR Program are likely to change with time. The approach used in the Virginia Medicaid DUR Program is to start with requirements that can be reasonably accomplished by the majority of pharmacy providers.

While the following information on prospective screening is meant to serve as a guide for ProDUR activities for Virginia Medicaid providers, it should not be construed to be an all-encompassing document. Pharmacists, and other Medicaid providers, are expected to exert their clinical judgement in dealing with the types of problems outlined below.

Therapeutic Duplication

Therapeutic duplication means the concomitant use of two or more drugs having the same or very similar pharmacologic properties. In some circumstances, therapeutic duplication may be appropriate (e.g., the use of more than one antihypertensive to treat difficult-to-control hypertension). However, in many situations, therapeutic duplication has the potential for causing the patient harm as a result of drug interactions, additive toxicity, and/or enhanced pharmacologic effects and represents unnecessary expenditure of health care resources.

Drug-Disease Contraindications

Drug-disease contraindications identified by reference to medical claims data in the system. Alerts will be sent when appropriate.

Drug-Drug Interactions

Drug-drug interactions may involve both prescription and non-prescription drugs.

Incorrect Drug Dosage or Duration of Drug Treatment

Incorrect drug dosage or duration of drug treatment is a type of problem that may be difficult to screen for because of lack of information about diagnoses, patient response to therapy, and hepatic and/or renal function. Where possible, the MMIS system will identify these problems based on data submitted through the claims process.

Drug-Allergy Interactions

All pharmacists should have the ability to screen for this type of therapy problem in-house. Medicaid does not collect allergy data, so this review must be done on-site. It is important to remember that what may be called an allergy by a patient is often an adverse reaction or a side effect (e.g., most codeine/morphine allergies are really reports of adverse GI effects of the drug). When requesting allergy information, be sure to also ask, "what happened?" Reports of shortness of breath or skin rashes are usually indicative of true allergic reactions. Reports of GI upset (nausea, vomiting, diarrhea, etc.) and CNS disturbances (feeling "funny" or feeling sleepy) are generally the results of side effects. This does not mean that side effects are to be trivialized and ignored. Rather, the patient should be educated as to the true nature of these undesirable results of drug therapy and encouraged to discuss them with the prescriber. More often than not, other therapeutic alternatives are available. Pharmacists should be vigilant for potential cross-sensitivity concerns when therapeutic alternatives are considered within classes of drugs (e.g., NSAIDs) and across classes of drugs (e.g., penicillins and cephalosporins).

Clinical Abuse/Misuse

Clinical abuse/misuse is the occurrence of any of the situations referred to in the definitions of abuse, gross overuse, overutilization, and underutilization, and incorrect dosage and duration:

- **Abuse** means practices that are inconsistent with sound fiscal, business, or medical practices and result in unnecessary costs to the Virginia Medicaid Program or reimbursement for services that are not medically necessary or reimbursement for services that fail to meet professionally recognized standards for health care.

- **Gross overuse** means repetitive overutilization without therapeutic benefit.

- **Overutilization** means use of a drug in quantities or duration that put the recipient at risk of an adverse medical condition.

- **Underutilization** means use of a drug by a recipient in insufficient quantity to achieve a desired therapeutic goal.

- **Incorrect drug dosage** means the dosage lies outside the daily dosage range

(i.e., under dosage and excessive dosage) specified in predetermined standards (i.e., the manufacturer's dosage information or the USPDI) as necessary to achieve therapeutic benefit. Dosage range is the strength multiplied by the quantity dispensed divided by the days' supply.

- **Incorrect duration of drug treatment** means the number of days of prescribed therapy exceeds or falls short of the recommendations contained in the predetermined standards.

Summary of the Drugs and Drug Classes to be Covered by ProDUR

The criteria for the retrospective and prospective components of the DUR Program should be consistent if maximum benefit is to be derived from the Program. As previously noted, the retrospective DUR criteria are representative of clinically important issues with a focus on high-risk, high-volume, and high-cost drugs. Thus, criteria very similar to those developed for retrospective DUR will be used for ProDUR.

Patient Counseling Activities

The State statute regarding patient counseling allows for a broader interpretation of what constitutes an "offer to counsel" than OBRA '90. The original intent of the OBRA '90 patient counseling mandate was for the pharmacist to make a verbal offer to discuss the medication to be dispensed with the Medicaid recipient or his or her agent.

Please note that:

- The pharmacist may delegate the responsibility of offering the counseling to a non-pharmacist; however, the actual responsibility for patient counseling may not be delegated to anyone except a pharmacy intern working under the supervision of a pharmacist.

- Printed materials may be used to **supplement** patient counseling, but **may not** be used **in place of** verbal counseling.

Both the State statute and OBRA '90 also require that the information provided to recipients include, but not be limited to, the following:

- Name and description of medication;

- Dosage form, dosage, route of administration, and duration of therapy;

- Special directions and precautions for preparation, administration, and use by the patient;

- Common adverse or severe side effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

- Techniques for self-monitoring drug therapy;
- Proper storage;
- Prescription refill information; and
- Action to be taken in the event of a missed dose.

The pharmacist should use his or her professional judgement as to the amount of information to provide in each area. The pharmacist must provide complete and thorough counseling before dispensing **all new** prescriptions. The degree of counseling to be provided before dispensing **refills** is subject to the pharmacist's discretion. The recipient or his or her agent may refuse counseling; however, the offer to counsel should not be presented in such a way as to encourage refusal of counseling. The acceptance or refusal of the offer to counsel should be documented, preferably in the patient's profile (see below).

Patient Profile Activities

Both OBRA '90 and the State ProDUR/patient counseling/patient profiling statute require that the following information be included in the patient's profile:

- Patient's name, address, telephone number, date of birth (or current age), and gender;
- Medical history, including:
  - Disease state(s)
  - Known allergies and drug reactions
  - A comprehensive list of medications and relevant devices
- Pharmacist's comments relevant to the patient's drug use, including any failure to accept the pharmacist's offer to counsel.

Documentation of ProDUR Activities

DMAS will document the performance of ProDUR screening by follow-up of the ProDUR criteria using the retrospective DUR software. A prescription signature log may be used to document the acceptance or rejection of the offer to counsel. However, it is recommended that the performance of patient counseling activities and an assessment of the impact of the activities be documented in the patient's profile by the pharmacist.

Provider Profiling

Evaluation of claims-based data is also used to determine the presence of providers who receive a high number of alerts for unusual prescription use. Using the RetroDUR process, the system is programmed to collate the alerts generated for each prescriber or pharmacy. The DUR Board then determines which types of alerts are to be focused upon and sets the point for exceptions to trigger the system generation of a provider letter. Information conveyed to providers in this program reinforces the norms established for prescribing/dispensing of the classes or products in question.

Providers are asked to respond to a questionnaire regarding reasons for the documented pattern of care. Provider profiling is a useful tool in identifying prescribers and dispensers who may need educational intervention(s) related to potentially harmful therapeutic decisions.

DISEASE STATE MANAGEMENT INITIATIVE

DMAS has been a national leader in the implementation of proactive programs to improve patient health and quality of life, while conserving precious resources. The practitioners of the healing professions within the Commonwealth have participated to make the attempts reach successful outcomes.

A voluntary initiative to educate providers and increase awareness of the appropriate use of antiulcer drugs was launched in the early days of the DUR program. Millions of dollars were saved through the program and it became apparent that providers could work together with DMAS to achieve quality health care and cost saving simultaneously. Partly as a result of the attention this program received, DMAS was asked to participate in a joint effort known as the Virginia Health Outcomes Partnership (VHOP). Through an educational grant from the National Pharmaceutical Council, and in conjunction with various professional organizations and educational institutions, DMAS began to work with the Williamson Institute at the Medical College of Virginia campus of Virginia Commonwealth University. While the training programs developed by that partnership effort were restricted to a small number of providers, the concepts used in the program were found to create a positive impact on the health of a cadre of patients suffering from asthma, while generating cost savings downstream in the use of valuable resources such as ER visits and hospitalizations. The positive tone of the documented outcomes created a favorable environment for the development of an on-going program. In November of 1997, Heritage Information Systems of Richmond was awarded a contract to develop and operate a Disease State Management program under the guidance of DMAS.

Virginia's Disease State Management program relies heavily on the pharmacists of the Commonwealth for providing interventions with at-risk patients identified in the program. After development was completed in the spring of 1999, pharmacists and physicians were trained by way of a statewide satellite-enabled, interactive program developed by HIS. Patients identified by the system as at-risk are asked to provide a baseline Quality of Life and Risk Assessment through surveys provided through the participating pharmacist.

Documentation for at-risk patients is sent quarterly to the patient's pharmacist(s) and physician(s) identified through system edits. Included is a condensed version of the appropriate national guidelines for each of the targeted disease states: Asthma/COPD, Hypertension/Congestive Heart Failure, GERD/Peptic Ulcer Disease, Diabetes, and Depression. Providers are notified as to the particular risk factors for the disease(s) the patient is experiencing. Providers are requested to document the extent of intervention provided. In the early fall of 2000, a comparison will be made of surveys filled out by patients and include the documented claims history of the patients involved in the program.

A control group will be compared with the target audience and the first set of outcomes analysis results are expected in the fall of 2000.

Through updates to the on-line claims adjudication (POS) system, providers are alerted to the need for intervention with targeted patients.